भारतीय मानक **IS 4739 : 2023**

Indian Standard

चिकित्सीय वस्त्रादि — जिंक ऑक्साइड इलास्टिक आसंजक पट्टी — विशिष्टि

(दूसरा पुनरीक्षण)

Medical Textiles — Zinc Oxide Elastic Adhesive Bandage — Specification

(Second Revision)

ICS 11.140;59.080.01

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October 2023 **Price Group 6**

Technical Textiles for Medtech Applications Sectional Committee, TXD 36

FOREWORD

This Indian Standard (Second Revision) was adopted by the Bureau of Indian Standards, after the draft finalized by the Technical Textiles for Medtech Applications Sectional Committee had been approved by the Textiles Division Council.

This standard was first published in 1968 and subsequently revised in 1986. This revision has been made in the light of experience gained since its publication and to incorporate the following major changes:

a) The title of the standard has been modified;
b) Amendments have been incorporated;
c) The tolerance for the weight, end per dm, picks per dm have been modified;
d) Test method for weight has been modified;
e) Additional dimension of width of bandage have been specified;
f) The method of test for stretchability/elasticity has been updated;
g) The additional requirement of *p*H test has been specified;
h) The test method and minimum requirement of adhesion strength of plaster has been modified;
j) Reference to Indian standards have been updated;
k) BIS certification marking clause has been updated; and
m) Marking and packing clauses have been updated.

Zinc oxide elastic adhesive bandage consists of a plain or needle loom weave elastic cloth spread evenly on one side with a adhesive mass containing zinc oxide. This bandage adheres closely to skin at body temperature and does not require warming before application.

It is used to give light support and compression in case of fractured ribs or clavicles, in sprained joints, varicose veins and leg ulcers. It is also used to secure dressings and appliances.

The composition of the Committee responsible for the formulation of this standard is given in Annex E.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 2022 ‘Rules for rounding off numerical values (*second revision*)’. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

MEDICAL TEXTILES — ZINC OXIDE ELASTIC ADHESIVE BANDAGE — SPECIFICATION

(Second Revision)

1 SCOPE

This standard cover requirements pertaining to the material, construction and performance of zinc oxide elastic adhesive bandage.

2 REFERENCES

The standards listed in Annex A contain provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of these standards.

3 MATERIALS

3.1 Basic Cloth

3.1.1 Basic cloth shall be plain-woven cotton cloth. The weft threads can be soft-spun cotton or rayon or combination of cotton and rayon. It shall be reasonably free from spinning, weaving and processing defects. The cloth shall be bleached white or tinted flesh with a suitable dye. The edges of the bandage may be indicated as fast edges.

3.1.2 The cloth shall be woven two threads right twist (Z) and two threads reverse twist (S) along the warp. It shall conform to particulars given in Table 1.

Table 1 Manufacturing Particulars of Basic Cloth

(*Clause* 3.1.2)

Sl No.	**Universal Count (Cotton Count) of Yarn (Approx) (*see* Note)**		**Ends Per Dm,** *Min*	**Picks Per Dm,** *Min*	**Minimum No of Turns Per cm (*see* Note)**		**Weight** g/m^2, *Min*
	Warp	Weft			Warp	Weft	
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
i)	23 tex × 2 (or 26s/2)	70 tex × 2 (or 8s/2)	174	80	18	–	140
Method of Test, Ref to	–	–	IS 1963		IS 832 (Part 1) or IS 832 (Part 2)		IS 14944

NOTE — Count and turn per count are given for guidance purpose only.

3.2 Adhesive Material

It shall be adhesive mass containing zinc oxide and free from toxic material and material known to be injurious to cloth.

4 DIMENSIONS

The stretched bandage shall be either of the following sizes:

Sl No.	*Width* cm	*Length (stretched)* m
(1)	(2)	(3)
i)	5	4 to 6
ii)	6	
iii)	7.5	
iv)	8	
v)	10	
vi)	15	

The stretched length and width shall not be less than 95 percent of the stated length and width respectively when tested by the stretchability/elasticity test as specified in IS 14944.

NOTE — Other dimensions as agreed between the buyer and the seller may also be permitted.

5 MANUFACTURE

5.1 The adhesive mass shall be spread evenly and uniformly over the bandage and shall not be less than 120 gm/m^2 when tested according to method given in Annex B and calculated from unstretched width and fully-stretched length.

5.2 Zinc oxide content shall be not less than 10 percent, calculated as zinc oxide, when determined according to method given in IS 14944.

6 PERFORMANCE

6.1 Stretchability and Recovery

6.1.1 *Stretchability*

The stretchability of the bandage shall not be less than 65 percent when tested according to method given in Annex C.

6.1.2 *Recovery*

The length of the test specimen of the stretched bandage after release shall not be more than four-fifths of the stretched length when determined according to method given in Annex C.

6.2 Adhesive Strength

The adhesive strength of plaster shall be minimum 100 g/cm when tested as per method given in IS 14944.

6.3 *p*H Test

The zinc oxide elastic adhesive bandage shall have the *p*H value (aqueous extract) between 6.5 to 8.5 when determined as per method given in IS 1390.

7 TESTS

7.1 Test for various requirements shall be conducted as prescribed in appropriate annex and relevant clauses of this standard.

7.2 Conditioning

Each roll selected for test shall be conditioned for a minimum period of 24 hrs at (27 ± 2) °C and (65 ± 2) percent relative humidity (*see* IS 196) prior to testing and testing shall be in the same atmosphere. When the tests cannot be carried out in the same atmosphere, then the testing shall be commenced within 2 min of withdrawal of the specimens from the conditioning atmosphere.

7.3 The three outer layers of each roll shall be discarded before taking specimens for test.

7.4 All specimens shall be removed from the roll at an approximate speed of 30 cm/min.

7.5 The adhesive surface shall not be permitted to come in contact with the fingers, or to be contaminated with dust, or to come in contact with foreign matter.

8 PACKING

8.1 The zinc oxide elastic adhesive bandage shall be wound on a spool, wrapped in suitable paper and packed in suitable containers as agreed to between the purchaser and the manufacturer.

8.2 The zinc oxide elastic adhesive bandage shall be packed securely so as to allow normal handling and transport without tearing and exposing the contents. Details of the packing shall be as agreed to between the buyer and the seller. Packaging of the product shall be such as to maintain the integrity of the product throughout its shelf life.

9 SAMPLING AND CRITERIA FOR CONFORMITY

Sampling and acceptance criteria for zinc oxide elastic adhesive bandage shall be as agreed to between the purchaser and the supplier. A recommended scheme for the same has been given in Annex D.

10 MARKING

10.1 Each container/package shall be legibly and indelibly marked with the following information:

a) Manufacturer's name, trade-mark, and manufacturing licence number;
b) Name of the bandage;
c) Size of the bandage;
d) Date of manufacture and batch number;
e) If the cloth is dyed, the name of the colour should be stated on the label;
f) If the adhesive is made porous, it shall be stated on the label; and
g) Any other statutory requirement as required by the law in force or as agreed between buyer and seller.

10.2 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the products may be marked with the Standard Mark.

ANNEX A

(*Clause* 2)

LIST OF REFERRED STANDARDS

IS No.	*Title*
IS 196 : 1966	Atmospheric conditions for testing (*revised*)
IS 264 : 2005	Nitric acid — Specification (*third revision*)
IS 460 (Part 1) : 2020	Test sieves — Specification: Part 1 Wire cloth test sieves (*fourth revision*)
IS 832	Textiles — Determination of twist in yarns
(Part 1) : 2021	Direct counting method
(Part 2) : 2011	Untwist retwist method for single spun yarns (*second revision*)
IS 1390 : 2022	Textiles — Determination of *p*H of aqueous extract (*third revision*)
IS 1963 : 1981	Methods for determination of threads per unit length in woven fabrics (*second revision*)
IS 4905 : 2015	Random sampling and randomization procedures (*first revision*)
IS 14944 : 2020	Surgical dressings — Methods of test (*first revision*)

ANNEX B

(*Clause* 5.1 *and Table* 1)

DETERMINATION OF WEIGHT OF CLOTH AND WEIGHT OF ADHESIVE MASS

B-1 TEST SPECIMEN

B-1.1 Cut about 10 g of the sample from the sample and weigh it accurately. Take care to cut parallel to the warp and weft threads.

B-2 PROCEDURE

B-2.1 Measure the area of the specimen accurately and extract with chloroform in a Soxhlet extractor until the adhesive mass completely disintegrates. Take out the fabric, dry to remove residual chloroform and immerse in dilute acetic acid for 3 hrs. Remove sample in a suitable vessel and wash 12 times with boiling water, using 1 000 ml for each washing. Pass wash water through 150 micron IS Sieve [*see* IS 460 (Part 1)] to collect any loose fibres. Dry the residue to constant weight at (100 ± 2) °C and correct the weight for moisture regain.

B-2.2 Calculate the weight of fabric in g/m2. Calculate weight of the adhesive mass in g/m2 by subtracting the weight of the fabric from the weight of sample originally taken as given below:

$$\text{Weight of adhesive mass} = \frac{W-w}{A}\ \text{g/m}^2$$

where

W = weight in grams of the sample taken;

w = weight in grams of the residual fabric corrected by moisture regain; and

A = area in square metre of the sample taken.

Correction for moisture regain = 8.53 percent.

ANNEX C

(*Clauses* 6.1.1 *and* 6.1.2)

METHOD FOR DETERMINATION OF STRETCHABILITY AND RECOVERY

C-1 PREPARATION OF TEST SPECIMEN

C-1.1 Cut three test strips of a length of 30 cm from the bandage. Mark two parallel lines across the piece at a distance of 20 cm from each other, starting at a distance of 5 cm from one end.

C-2 PROCEDURE

C-2.1 Stretchability

Fix one end of the material in a fixed grip and other in a movable grip in such a way that the gauge marks are visible between the grips and the material can stretch longitudinally (crepe yarn way). Suspend a load of 1 kg/cm width on the movable grip (weight of movable grip shall be taken into account) for a period of one minute and determine the stretched length between the marks. Express the increase in length as percentage of the unstretched length of the sample.

C-2.2 Recovery

Keep the fabric under tension of 1 kgf/cm width for one minute as given in **C-2.1**. Remove the fabric from grips and lay on a smooth flat surface without any tension. After 5 min, measure the distance between the two marks.

ANNEX D

(*Clause* 9.1)

SAMPLING AND CRITERIA FOR CONFORMITY FOR ZINC OXIDE ADHESIVE PLASTER

D-1 Lot

D-1.1 In any consignment, all spools of zinc oxide adhesive plaster of similar size produced under similar conditions shall constitute a lot.

D-l.2 The number of spools to be selected from each lot shall depend upon the size of the lot and shall be in accordance with col (1) and (2) of Table 2.

D-1.2.1 These spools shall be selected from the lot at random and in order to ensure the randomness of selection, procedures given in IS 4905 shall be adopted.

D-2 NUMBER OF TESTS AND CRITERIA FOR CONFORMITY

D-2.1 The number of spools selected at random in accordance with col (2) of Table 2 shall be tested for dimensions **4.1**. The lot shall be considered as conforming to this requirement if the number of defectives found in the sample is less than or equal to the corresponding acceptance number of defectives as given in col (3) of Table 2.

D-2.2 If the lot is conforming to the requirements as mentioned in **D-2.1** the test for weight of adhesive mass **5.1**, zinc oxide content **5.2**, tensile strength of plaster **6.1**, adhesive property **6.2**, *p*H test **6.3** and conditioning **7.2** shall be carried out. The number of times each test to be repeated shall be in accordance with col (1) and (2) of Table 3. If the sample passes each number of times, the lot shall be considered as conforming to these tests.

D-2.3 The lot shall be considered as conforming to the standard if **D-2.1** and **D-2.2** are satisfied.

Table 2 Sample Size and Criteria for Conformity

(*Clause* D-1.2)

Sl No. (1)	Lot Size (2)	Sample Size (3)	Acceptance Number (4)
i)	Up to 300	13	1
ii)	301 to 500	13	1
iii)	501 to 1 000	20	2
iv)	1 001 to 3 000	32	3
v)	3 001 to 10 000	32	3
vi)	10 001 to 35 000	50	5
vii)	35 001 and above	80	7

Table 3 For Manufacture, Performance Requirements and Conditioning Tests

(*Clause* D-2.2)

Sl No. (1)	Lot Size (2)	Number of Times Tests to be Repeated (3)
i)	Up to 500	1
ii)	501 to 1 000	2
iii)	1 001 to 3 000	3
iv)	3 001 to 10 000	4
v)	10 001 and above	5

ANNEX E

(*Foreword*)

COMMITTEE COMPOSITION

Technical Textiles for Medtech Applications, TXD 36

Organization	*Representative(s)*
The South India Textile Research Association, Coimbatore	Dr Prakash Vasudevan **(*Chairperson*)**
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The Synthetics & Art Silk Mills Research Association, Mumbai	Dr Manisha Mathur Shrimati S. S. Dongre (*Alternate*)

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This Indian Standard has been developed from Doc No.: TXD 36 (21302).

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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Published by BIS, New Delhi